

DETAILED ACTION

Response to Amendment

This office action is in response to the amendment filed on December 16, 2009. Claims 8-10, 13, 17, 20, and 23 have been amended. Claims 24 and 25 have been added. Claims 8-25 are pending and addressed below.

Claim Objections

Claim 16 is objected to because of the following informalities: "return springs" should be singular, not plural. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 10, applicant refers to a "distal edge" in line 4, but does not give a point of reference to determine which edge is the "distal edge."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8, 11, 12, 14, 15, 17-21, and 23 are rejected under 35 U.S.C. 102(b) as being

anticipated by Czernecki et al. (US 5356420), hereinafter referred to as “Czernecki.” Czernecki was cited in the previous office action.

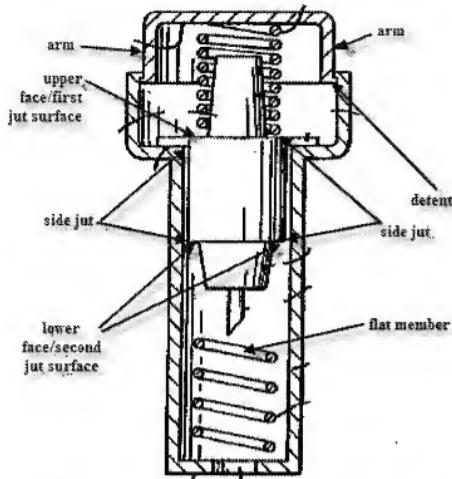


Image 1 from Czernecki Fig. 1

Regarding claims 8, 11, 12, 14, 15, 17-21, and 23, Czernecki discloses a puncturing device comprising: a housing (Fig. 1, [1]), wherein the housing defines a breaking edge (Fig. 1, [12]); a puncturing needle disposed in the housing (Fig. 1, [5]), wherein the puncturing needle has breakable wings that rest against the breaking edge of the housing (Fig. 1, [11]), and at least one side jut (see Image 1 above); a push button disposed in the housing (Fig. 1, [2]), wherein the

push button has arms to guide the push button inside the housing (see Image 1 above); at least one return spring (Fig. 1, [10]), wherein each of the at least one return spring is connected to an arm of the arms (connected to the arms via the housing 1, as “connected” does not necessitate direct contact), and wherein the at least one return spring has a contact portion that contacts the at least one side jut (see Fig. 2); and a driving spring having a first end and a second end (Fig. 1, [9]), wherein the first end is linked to the push button and the second end drives the puncturing needle in a driving direction parallel to a longitudinal axis defined by the puncturing needle (see Figs. 1 and 2); wherein the entirety of the at least one side jut of the puncturing needle is disposed inside the housing longitudinally between the contact portion of the last least one return spring and the second end of the driving spring before, during, and after use of the puncturing device, such that the contact portion of the at least one return spring, the entirety of the at least one side jut, and the driving spring are disposed in non-overlapping series along the longitudinal axis before, during, and after use of the puncturing device (see Figs. 1 and 2); and wherein the at least one return spring acts against the at least one side jut in a direction generally opposite to the driving direction (see Fig. 2);

wherein the first end of the driving spring is integrally connected to an inside face of the push button (see Fig. 1);

wherein the second end of the driving spring comprises a pusher that pushes the puncturing needle (Fig. 2, the end coil of the second end of the driving spring 9 that contacts the needle 5 comprises the pusher);

wherein the pusher has a cup-shaped end (see Fig. 1, wherein the second end of the drive spring 9, which comprises the pusher, has a cup-like opening) and wherein the puncturing needle has a projection that fits within the cup-shaped end of the pusher (Fig. 1, [6]);

wherein the driving spring is shaped like the letter “S” (see Fig. 2, wherein the spring forms an “S” shape as the spring coils);

wherein a first force applied to the push button compresses the driving spring between the push button and the puncturing needle (see Fig. 1) and presses the breakable wings against the breaking edge until the breakable wings break (see Figs. 1 and 2; column 2, lines 35-58); wherein, upon breaking the breakable wings, the driving spring drives the puncturing needle such that a lancet of the puncturing needle extends outside the housing and the at least one side jut contacts the at least one return spring (see Fig. 2; column 2, lines 35-58), and wherein, after the lancet extends outside the housing, the at least one return spring applies a second force to the at least one side jut in a direction generally parallel to the longitudinal axis and opposite to the first force to pull the lancet on the puncturing needle inside the housing (see Fig. 2);

wherein after pulling the lancet of the puncturing needle inside the housing, the at least one return spring and the driving spring are in a free state (see Fig. 2, wherein the springs are relaxed after the firing and returning of the needle 5);

wherein the arms are integral to the push button before, during, and after use of the puncturing device (see Figs. 1 and 2);

wherein each of the arms of the push button defines a detent contained within the housing, wherein the detent contacts an interior portion of the housing to prevent removal of the push button from the housing (see Image 1 above), and wherein the each of the at least one

return spring is connected to the detent of the arm (connected to the arms via the housing 1, as “connected” does not necessitate direct contact); and

wherein the puncturing needle has a first end driven by the driving spring and a second end comprising a puncturing portion (see Fig. 1), wherein the at least one side jut is disposed on the puncturing needle proximate to the first end of the puncturing needle and proximate to the second end of the driving spring (see Image 1 above, wherein the jut is near the first end of the needle 5 and the second end of the drive spring 9) (wherein “proximate” means “close; very near” according to <http://www.dictionary.com>).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 9, 10, 22, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Czernecki (US 5356420).

Regarding claims 9 and 10, Czernecki discloses the puncturing device according to claim 8, wherein the at least one side jut comprises two side juts (see Image 1 above, wherein there is a jut on both the right and left sides of the needle), each of which is positioned inside the device longitudinally between the contact portions of the return spring and the second end of the driving spring before, during, and after use of the puncturing device, such that the return spring, the two side juts, and the driving spring are disposed in series along the longitudinal axis before, during, and after use of the puncturing device (see Figs. 1 and 2);

wherein the two side juts each comprises an elongate member that extends perpendicularly to the longitudinal axis and defines a first jut surface facing the driving spring, and a second jut surface opposite to the first surface, and a distal edge (see Image 1 above), wherein the return spring is connected approximately perpendicularly to the lower portions of the arms of the push of the push button (see Fig. 1, wherein the spring members are approximately perpendicular to the arms), wherein the return spring comprises a flat member defining a plane (see Image 1 above), wherein the flat member extends toward the puncturing needle such that the plane of the flat member is generally perpendicular to and generally radial to the longitudinal axis (when the return spring 10 is compressed at the point the puncturing portion 7 of the needle extends through the aperture 4, the flat member has a plane nearly perpendicular to the longitudinal axis, while the flat member is still slightly extending towards the needle; note that the term "generally" does not mean the plane *is* perpendicular to the longitudinal axis), wherein the flat member defines a first return spring surface facing the second jut surface and the second return spring surface opposite to the first return spring surface (see Image 1 above), wherein the first return spring surface and the second jut surface remain facing each other before, during, and

after use of the puncturing device (see Figs. 1 and 2), and wherein the first return spring surface contacts the second jut surface to move the puncturing needle in a direction opposite to the driving direction and parallel to the longitudinal axis (see Fig. 2); but not wherein the at least one spring comprises two return springs.

However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add a second return spring, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Regarding claim 22, Czernecki discloses the puncturing device according to claim 8, wherein the puncturing needle has a first end driven by the driving spring (see Fig. 1) and a second end comprising a puncturing portion (Fig. 1, [7]), a side jut disposed on the puncturing needle (see Image 1 above), and breakable wings disposed on the puncturing needle (Fig. 1, [11]), but not wherein the at least one side jut is disposed on the puncturing needle closer to the first end of the puncturing needle than the second end of the puncturing needle, and wherein the breakable wings are disposed on the puncturing needle closer to the second end of the puncturing needle than the first end of the puncturing needle.

However, it would have been obvious to one having ordinary skill in the art at the time the invention was made rearrange the breakable wings and at least one side jut as claimed, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

Regarding claim 24, Czernecki discloses a puncturing device comprising: a housing (Fig. 1, [1]), wherein the housing defines a breaking edge (Fig. 1, [12]); a puncturing needle disposed in

the housing, wherein the puncturing needle defines a longitudinal axis along which the puncturing needle travels, and wherein the puncturing needle comprises: an elongate body extending longitudinally (Fig. 1, [5]); a breakable wing protruding from the body in a direction perpendicular to the longitudinal axis, wherein the breakable wing rests against the breaking edge of the housing before use of the puncturing device (Fig. 1, [11]), and a jut member protruding from the body in the direction perpendicular to the longitudinal axis (see Image 1 above), wherein the jut member defines a lower contact face facing the puncturing end of the needle (see Fig. 1) and an upper face opposite the lower contact face (see Image 1 above); a push button disposed in the housing, the bush button comprising: a button face extending in a direction perpendicular to the longitudinal axis and disposed over the upper pushing end of the puncturing needle (Fig. 1, [8]), an arm extending from the button face in a direction toward the lower puncturing end of the puncturing needle and parallel to the longitudinal axis, wherein the arm guides movement of the push button within the housing (see Image 1 above, and Figs. 1 and 2 for the movement), and a return spring connected to the arm (Fig. 1, [10], connected to the arms via the housing 1, as “connected” does not necessitate direct contact), the return spring defining an upper contact surface that contacts the lower contact face of the jut member (see Fig. 2); and a driving spring disposed between the button face of the push button and the pushing end of the puncturing needle (Fig. 1, [9]), wherein the driving spring is discontinuous with the puncturing needle (the drive spring 9 is not integrally formed with the pushing end of the needle), and wherein before, during, and after use of the puncturing device, the lower contact surface of the jut member faces the upper contact surface of the return spring (see Figs. 1 and 2);

but does not disclose wherein the breakable wing is disposed closer to the puncturing end than the jut member.

However, it would have been obvious to one having ordinary skill in the art at the time the invention was made make the breakable wings disposed closer to the puncturing end than the jut member, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

With regards to the rearrangement of parts, one of ordinary skill would understand the breaking edge in the housing must be relatively located to the breakable wings such that the breakable wings rest on the breakable edge prior to firing, and such rearrangement does not alter the functionality of the breaking edge and breakable wings, nor the functionality of the device as a whole.

Claims 13, 16, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Czernecki (US 5356420) as applied to claims 8, 12, and 24 above, and further in view of Burns (US 4527561).

Regarding claim 13, Czernecki discloses the puncturing device according to claim 12, but not wherein the puncturing needle and the pusher are separate structures, wherein the pusher contacts the puncturing needle during operation of the puncturing device, and discontinues contact with the puncturing needle after use such that the pusher becomes discontinuous with the puncturing needle after use.

However, Burns teaches wherein the puncturing needle (Fig. 26, [210]) and the pusher (Fig. 26, the last coil on the second end of the drive spring 211) are separate structures, wherein

the pusher contacts the puncturing needle during operation of the puncturing device (see Fig. 25), and discontinues contact with the puncturing needle after use such that the pusher becomes discontinuous with the puncturing needle after use (see Fig. 27).

Regarding claim 25, Czernecki discloses the puncturing device of claim 24, but not wherein during the use of the puncturing device, the driving spring and the puncturing needle separate from each other such that a gap exists between the drive spring and the puncturing needle.

However, Burns teaches wherein during the use of the puncturing device, the driving spring and the puncturing needle separate from each other such that a gap exists between the drive spring and the puncturing needle (see Figs. 26 and 27).

It would have been obvious to combine the discontinuous contact between the pusher and the needle of Burns with the puncturing device of Czernecki because such an arrangement does not require a balancing of the drive and return spring (Burns, column 11, lines 3-4). The motivation for the modification would have been to allow for a more straightforward operation, reduction of the spring sizes, and lighten the weight of the materials (Burns, column 11, lines 4-6).

Regarding claim 16, Czernecki discloses the puncturing device according to claim 8, but not wherein the return spring is a flat spring.

However, Burns discloses a return spring comprising a flat spring (Fig. 21, [124]).

Because both Czernecki and Burns both teach a return spring, it would have been *prima facie* obvious to one skilled in the art to substitute one return spring for the other to achieve the predictable result of returning the puncturing portion of the lancet to a position inside the

housing. Express suggestion to substitute one equivalent for another need not be present to render such substitution obvious. *In re Fout*, 675 F.2d 297.

Response to Arguments

Applicant's arguments with respect to claims 8-23 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JONATHAN W. MILES whose telephone number is (571)270-7777. The examiner can normally be reached on Monday-Thursday 7:30 am-5:00 pm.

Art Unit: 3731

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571)272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Jwm

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